DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-261/S-097

ESP PHARMA
Attention: Richard J. Brown, MD
Chief Regulatory Officer
2035 Lincoln Highway, Suite 2150
Edison, NJ 08817

Dear Dr. Brown:

Please refer to your supplemental new drug application dated October 31, 2003, received November 3, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Declomycin® (demeclocycline hydrochloride) Tablets.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for revised labeling to comply with the Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We completed our review of this supplemental new drug application and it is approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 31, 2003, and with the corrected text as described below:

> In the PRECAUTIONS section, Information for Patients subsection, last paragraph, 1st sentence, add the word "only" as follows:
>
> > "Patients should be counseled that antibacterial drugs including Declomycin (demeclocycline hydrochloride) Tablets, should only be used to treat bacterial infections"

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth

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